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	Re: Appeal to the Board of Pate	ent Appeals and Interference	es	IFW
Application of	Re: Appeal to the Board of Pate Donald J. McMichael, et al.	Group Art Unit:	3728	1

In re	Application of:	Donald J. McMichael, et al.	Group Art Unit:	3728	
Seria	ıl No.:	10/085,637	Examiner:	Luan Kim Bui	
Filed	l:	February 28, 2002	Our Customer ID:	22827	
For:		Surgical Kit With Accessory Item Container	Our Account No:	04-1403	
Sir:			Attorney Ref:	KCX-518A (17507A	
<ol> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	[X] BRIE1 triplica An OF after E	RAL HEARING is respectfully requested u xaminer's Answer).	iner twice/finally rejec 7 CFR 1.192 is transmi nder 37 CFR 1.194 (du	ting claims itted herewith in	
4. 5. 6.	[ ] Reply [ ] "Small FEE CALCU	Brief under 37 CFR 1.193(b) is transmitted entity" verified statement filed: [ ] herewi	herewith in triplicate. th [ ] previously.	Fees	
	If box 2 above If box 3 above If box 4 above Petition is here	is X'd enter \$330.00 is X'd enter \$330.00 is X'd enter \$290.00 is X-d enter -0- (no fee)  by made to extend the <u>original</u> due date of to cover the date of this paper and for which the requisite fee is (1 month \$110		\$\$ \$330.00 \$\$	
	(2 months \$420	0); (3 months \$950); (4 months \$1,480).  Ous extension fee paid since above	Subtotal -	\$ <u>330.00</u> \$	
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[X] []	Fee enclosed.  Charge fee to our Deposit Account/Order Nos. in the heading hereof (for which purpose one additional copy of this sheet is attached)				
[]	Fee NOT required since paid in prior appeal in which the Board of Appeals did not render a decision on the merits.				
The Co	ommissioner is h	ereby authorized to charge any fee specificalled, or asserted to be filed, or which should	ally authorized hereafte have been filed herewi	er, or any fees in th or concerning any	

paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. show in the heading hereof for which purpose a duplicate copy of this sheet is attached. This statement does not authorize charge of the issue fee in this case.

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By: Neal P. Pierotti Signature:

Date: September 13, 2004

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, Post Office Box 1450, Alexandria, VA 22313-1450, on September 13, 2004.

Denise Bulkeley	
(Typed or printed name of person mailing paper or fee)	
Derul Kulle	
(Signature of person mailing paper or fee)	

ATTORNEY DOCKET NO: KCX-518A (17507A)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Donald J. McMichael, et al.	) Examiner: Luan Kim Bui
Serial No: 10/085,637	) Group Art Unit: 3728
Filed: February 28, 2002	) Deposit Account No: 04-1403
Confirmation No: 5368	) Customer No: 22827
For: Surgical Kit With Accessory Item Container	) )

# **APPEAL BRIEF**

Honorable Commissioner of Patents and Trademarks P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby submit this Appeal Brief in accordance with 37 C.F.R. § 1.192 for the above-captioned application. The Notice of Appeal was filed on August 19, 2004, in accordance with 37 C.F.R. § 1.8.

Applicants are submitting the filing fee for the filing of the present Appeal Brief as set forth in 37 C.F.R. § 1.17(c).

If any further fee or extension of time is required to obtain entry of the Appeal Brief, Applicants hereby petition the Commissioner to grant any necessary time extension, and the undersigned hereby authorizes the Commissioner to pay from Deposit Account Number 04-1403, any such fee not submitted herewith.

330.00 np

# 1. **REAL PARTY IN INTEREST:**

By assignment recorded on May 29, 2002, at reel 012936, frame 0182, the real party in interest is KIMBERLY-CLARK WORLDWIDE, INC., a corporation of the State of Delaware, whose internal address is 401 North Lake Street, Neenah, Wisconsin 54956.

# 2. RELATED APPEALS AND INTEREFERENCES:

There are no related appeals or interferences.

#### 3. STATUS OF CLAIMS:

The application was filed on February 28, 2002 with claims 1-26. Claims 1 and 15 were filed as independent claims.

By Amendment that was mailed on March 10, 2004, claims 1, 15 and 24 were amended.

The claims (1-23, 25 and 26) as amended are included in the attached Appendix.

Claims 1-23, 25, and 26 stand finally rejected (Advisory Action-Paper No. 20040723 mailed on July 28, 2004), under 35 U.S.C. § 103(a) as being unpatentable over Ross, et al. (U.S. Patent No. 5,318,543) in view of Harrison (U.S. Patent No. 5,392,918) and Rudnick, et al. (U.S. Patent No. 6,039,183). Regarding claim 15, the Advisory Action of July 26, 2004 indicated that claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Ross, et al. in view of Harrison and Rudnick, et al. and upon further modification of the combined references.

Claim 24 stands allowed (Advisory Action of July 28, 2004 and Paper No. 20040423-Office Action mailed April 27, 2004).

### 4. STATUS OF AMENDMENTS:

A Final Rejection was mailed in an Office Action on April 27, 2004 (Paper No.

20040423) rejecting claims 1-23, 25 and 26. Applicants mailed a Response on June 28, 2004 that traversed the rejection to claims 1-23, 25 and 26. Applicants Response was entered into the case by way of an Advisory Action mailed July 28, 2004 (Paper No. 20040723), but the Final rejection to claims 1-23, 25 and 26 was maintained.

#### 5. SUMMARY OF THE INVENTION:

The invention relates to a surgical kit that includes surgical implements and accessory items that are used in performing a particular surgical procedure such as percutaneous endoscopic gastrostomy.

Claims 1-14 are drawn generally to a surgical kit that includes a tray (Reference No. 22 in Figure 1) with a plurality of recesses and surfaces that may be used to hold various surgical articles and accessory surgical items. The surgical articles and accessory surgical items may be positioned in the tray so that the articles and items are presented to the user of the tray in their order of use for a particular surgical procedure.

The surgical kit also includes a substantially rigid accessory item container (Reference No. 24 in Figure 1) that is configured for holding objects, such as surgical articles and accessory surgical items, on only the inside of the container before being opened by a user. The container allows for generally loose accessory surgical items such as sutures, swabs, ointment packages, drapes, gauze pads, and the like to be held in a particular location for access by a user of the kit without moving under or being otherwise obscured and hidden from sight by other items or articles in the kit. The container may also serve as a receptacle in which used accessory surgical items or surgical articles may be placed in after use. In this manner, the container, along with the used accessory surgical items and surgical articles, may be disposed of by a user of

the surgical kit.

Claims 15-23, 25 and 26 are drawn generally to a percutaneous endoscopic gastrostomy kit that includes a tray, a container adapted to fit at least partially within the tray, and accessory items that include at least a drape that are stored in the container and used for performing the percutaneous endoscopic gastrostomy procedure. The surgical drape is stored by the container and, as such, is not placed loosely within the tray so as to become obscured when the user desires to make use of the drape.

#### 6. ISSUES:

Are claims 1-14 obvious under 35 U.S.C. § 103(a) by Ross, et al. in view of Harrison and Rudnick, et al.; and are claims 15-23, 25 and 26 obvious under 35 U.S.C. § 103(a) by Ross, et al. in view of Harrison and Rudnick, et al. and as further modified by one having ordinary skill in the art?

# 7. GROUPING OF CLAIMS:

Claims 1-14 rise or fall together. Claims 15-23, 25 and 26 rise or fall together.

#### 8. ARGUMENTS:

## **CLAIMS 1-14**

The Final Rejection to claims 1-14 will be addressed first. Each of the rejected claims 1-14 is drawn to a surgical kit that includes:

A substantially rigid accessory item container received in a container recess defined in the tray the container configured for holding objects only inside of the container before being opened by a user;

the container comprising a base member and lid configured with the base member, the container removable from the tray; and

a securing device configured between the base member and the lid.

A1. THE FINAL REJECTION FAILS TO PROVIDE THE REQUIRED SUGGESTION OR MOTIVATION TO COMBINE OR MODIFY THE ROSS, ET AL., HARRISON AND RUDNICK, ET AL. REFERENCES.

The first criteria that must be met to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. Manual of Patent Examining Procedure, 700-46 (8 Ed. Rev. 2 May 2004). It is necessary to ascertain whether the references' teachings are sufficient for one of ordinary skill in the relevant art having the references before him or her to make the proposed modification. *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (CCPA 1972). In the present case, there is no suggestion or motivation to modify the combination of Ross, et al., Harrison, and Rudnick, et al. as suggested by the Examiner to achieve Applicants' invention as set forth in claims 1-14, and there is no suggestion or motivation generally available to one of ordinary skill in the art to make the proposed combinations and modifications as stated by the Examiner.

Rudnick, et al. discloses a blister package assembly 20 that is configured for holding an aortic arch graft 10. Rudnick, et al. provides a blister insert 24 that is positioned on a blister tray 22 (see Rudnick, et al. at col. 4, II. 4-10). An outer surface of the blister insert 24 has a reverse blister depression 48 formed on one end (see Rudnick, et al. at col. 3, II. 44-47; and col. 4, II. 25-33). A lateral branch 16 of the aortic arch graft 10 is positioned and held in the reverse blister depression 48 in order to space and separate the lateral branch 15 from the aligned branches 14 of the aortic

arch graft 10. (See <u>Rudnick</u>, et al. at col. 4, II. 28-33). Nowhere does <u>Rudnick</u>, et al. disclose the holding of objects only inside of the blister insert 24. As can be seen, the blister insert 24 is specifically designed in order to hold objects on the surface thereof.

If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no proper suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1152 (Fed. Cir. 1984). In our case, modification of Rudnick, et al. so that the blister insert 24 holds the lateral branch 16 only inside of the blister insert 24 would make Rudnick, et al. unsatisfactory for its intended purpose because the lateral branch 16 forms a part of the aortic arch graft 10 and is in fact intricately formed therewith. As such, modification of Rudnick, et al. so that the lateral branch 16 was made to be held only inside of the blister insert 24 would in fact make it impossible for the blister insert 24 to support the lateral branch 16 which is in fact the entire point of the invention in Rudnick, et al. (see Rudnick, et al. at col. 2, II. 10-12).

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the reference are not sufficient to render the claims of Applicants' application *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959). Rudnick, et al. discloses a blister package assembly 20 in which the aortic arch graft 10 is located therein and in which the lateral branch 16 of the graft 10 is supported by the blister insert 24. Modification of Rudnick, et al. so that the blister insert 24 instead held the lateral branch 16 or the entire graft 10 inside would completely change the principle of operation of Rudnick, et al. because the blister insert 24 would no longer act to support

the lateral branch 16 but would instead act to house the lateral branch 16. Again, Rudnick, et al. seeks to provide a blister package that improves upon previous devises that were deemed to be incapable of supporting a complex-shaped aortic arch graft such as one with a lateral branch 16 (see Rudnick, et al. at col. 2, II. 1-4).

Turning now to Harrison, this reference discloses a sterile packaging that includes a tray and a holder for an intravascular guide-wire. The holder 26 includes an oval raceway 46 that is arranged in order to hold the guide-wire 22E in a compact, coiled condition (see Harrison at col. 4, II. 29-35). The guide-wire 22E is retained on both the inside and outside of the holder 26 as shown in Figure 7 of Harrison. The holder 26 includes an outlet passageway or port 48 through which the distal end of the guide-wire 22E extends (see Harrison at col. 4, II. 35-37). The port 48 holds a Jstraightener therein so the linearized distal free end of the guide-wire 22E can be readily inserted into an introducer 22B (see Harrison at col. 4, II. 47-50). This arrangement of the holder 26 allows the guide-wire 22E to be threaded out of the holder 26, and this arrangement also allows for the guide-wire 22E to be reversed so as to be pushed back through port 48 into the raceway 46 and therefore returned into holder 26 (see Harrison at col. 4, II. 50-57). Harrison explicitly states that this feature is of "considerable" importance" since it reduces the risk of contaminating others with a blood-coated guidewire 22E (see <u>Harrison</u> at col. 4, II. 59-61).

Modification of <u>Harrison</u> so that the holder 26 were configured to hold the guide-wire 22E only on the inside of the holder 26 would render <u>Harrison</u> unsatisfactory for its intended purpose. The entire point of holder 26 is to allow for the guide-wire 22E to be withdrawn from and then re-inserted into the holder 26 through port 48 when removed

from the patient's body. This object of <u>Harrison</u> would be completely frustrated if the holder 26 were to be configured so that the guide-wire 22E could not be at least partially held on the outside of the holder 26. Further, modification of <u>Harrison</u> in this manner would completely change the principle of operation of this reference. <u>Harrison</u> explicitly teaches that the use of port 48 in holder 26 to hold guide-wire 22E outside of the holder 26 is of "considerable importance" because guide-wire 22E is allowed to be re-inserted back into the interior of holder 26. Removal of this re-introduction feature would completely change the principle of operation of <u>Harrison</u> because doing so would remove a feature that is of "considerable importance" and would make it impossible to achieve reinsertion into the holder 26 in the manner taught in <u>Harrison</u>.

As such, both Rudnick, et al. and Harrison explicitly teach containers that are configured for holding objects at least partially on the outside of the container. Neither reference discloses a container in which the container is configured for holding objects only inside of the container before being opened by a user as set forth in claim 1 of Applicants' application. As stated by the Examiner in Paper No. 20040423, Ross, et al. does not disclose a container that is substantially rigid or that has a base member and a lid. As such, one having ordinary skill in the art would seek to incorporate either the blister insert 24 of Rudnick, et al. or the container 26 of Harrison into the tray of Ross, et al. Both Rudnick, et al. and Harrison specifically teach towards a blister insert or container in which objects are held at least partially on the outside of the container. Modification of the references so that the container was made to hold objects only on the inside would eliminate features that are of "considerable importance" and that would render the containers unsatisfactory for their intended purpose and change the principle

of operation of the containers in the references. Accordingly, there can be no suggestion or motivation to make the proposed modification. Consequently, a *prima* facie case of obviousness has not bee made.

A2. THE COMBINATION OF <u>ROSS</u>, <u>ET AL.</u>, <u>RUDNICK</u>, <u>ET AL.</u> AND <u>HARRISON</u> DOES NOT TEACH OR SUGGEST ALL OF THE CLAIM LIMITATIONS.

To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180, U.S.P.Q. 580 (CCPA 1974). In addition, all words in the claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970). Claims 1-14 of Applicants' application calls for a substantially rigid container that has a base member and a lid that is configured for holding objects only inside of the container before being opened by a user. This element is not taught or suggested by the combination of <u>Harrison</u>, <u>Rudnick</u>, et al., and Ross, et al.

Incorporation of the blister insert 24 of Rudnick, et al. and the holder 26 of Harrison into the sealed pouch 20 of Ross, et al. would produce a resulting device that includes a container configured for holding objects on the outside of the container. One having ordinary skill in the art upon combining these three references would replace the pouch 20 in Ross, et al. with the blister insert 24 of Rudnick, et al. or the holder 26 of Harrison or some combination of the two such that the resulting container includes a base member and a lid as taught by the references that is configured for holding objects on the outside thereof. As the pouch 20 in Ross, et al. does not include a base member

or a lid, these elements must be incorporated through the specific teachings of <u>Harrison</u> and <u>Rudnick</u>, et al. and as such would necessarily have to be configured so that the resulting container is configured for holding objects on the outside of the container. This is true because both <u>Harrison</u> and <u>Rudnick</u>, et al. specifically teach towards and require a container configured to hold objects on the outside. It is therefore the case that the Examiner has not found the recited claim elements in the prior art or provided a proper suggestion to modify the prior art to achieve the claimed invention. As such, a *prima* facie case of obviousness has not been made because all of the claim limitations have not been shown to be taught or suggested by the prior art.

Therefore, Applicants respectfully submit that independent claim 1 is patentable over the cited references. If an independent claim is non-obvious under 35 U.S.C. § 103(a), then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Dependent claims 2-14 in Applicants' invention depend directly or indirectly from independent claim 1 that is non-obvious under 35 U.S.C. § 103(a). Applicants therefore respectfully submit that claims 1-14 are patentable under 35 U.S.C. § 103(a) in view of the prior art.

#### **CLAIMS 15-23, 25 AND 26**

Each of the rejected claims 15-23, 25 and 26 is drawn to a percutaneous endoscopic gastrostomy kit that includes:

a container adapted to fit at least partially within a tray; and
wherein the container stores accessory items useful in performing the
percutaneous endoscopic gastrostomy procedure, and wherein the accessory items

include at least a drape.

B1. THE FINAL REJECTION FAILS TO PROVIDE THE REQUIRED SUGGESTION OR MOTIVATION TO COMBINE <u>RUDNICK</u>, <u>ET AL.</u>, <u>HARRISON</u> AND <u>ROSS</u>, <u>ET AL.</u> TO ACHIEVE A COMBINED DEVICE AND TO FURTHER MODIFIY THIS COMBINED DEVICE TO ACHIEVE THE INVENTION AS SET FORTH IN CLAIMS 15-23, 25 AND 26 OF APPLICANTS' APPLICATION.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill on the art. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). In the present case, there is no suggestion or motivation to combine Rudnick, et al., Harrison and Ross, et al. and then further modify this combined device as suggested by the Examiner to achieve Applicants' invention as set forth in claims 15-23, 25 and 26. In fact, there are specific teachings in the references to not modify the references as suggested by the Examiner in the Final Rejection (Paper No. 20040423).

Rudnick, et al. discloses a blister package 20 that is configured for holding an aortic arch graft 10. The blister insert 24 holds a lateral branch 16 of the aortic arch graft 10 in a reverse blister depression 48 on the outside surface of the blister insert 24 (see Rudnick, et al. at col. 4, II. 25-33; and Figure 2). Rudnick, et al. does not disclose a

container that stores accessory items that include at least a drape. Rudnick, et al. does not disclose a drape held in the blister package 20 or otherwise.

The holder 26 of <u>Harrison</u> is specifically designed with top and bottom sections 70, 72 in order to form a raceway 46 into which a guide-wire 22E may be stored, removed, and re-inserted (see <u>Harrison</u> at col. 7, II. 1-3; and col. 4, II. 50-61). <u>Harrison</u> does not disclose a container that stores accessory items that include at least a drape. In fact, modifying holder 26 so that it is capable of holding the drape would interfere with the ability of holder 26 to store, dispense, and receive the guide-wire 22E, and as such would completely frustrate the intended purpose of the holder 26 in <u>Harrison</u>.

Ross, et al. is the only reference of the three cited references that discloses a drape. Ross, et al. discloses a drape that is placed loosely in a first recess of the tray 13 (see Ross, et al. at col. 2, II. 38-43). Therefore, instead of suggesting to one of ordinary skill in the art to place the drape within a container that includes a base and reclosable lid, Ross, et al. specifically directs one of ordinary skill in the art to loosely place the drape into a recess in the tray 13.

unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). In the present case, Ross, et al. is specifically directed towards an instrumentation kit that reduces the amount of packaging of items in the kit (see Ross, et al. at col. 1, II. 42-45 and 56-59). The intended purpose of Ross, et al. is to provide for a kit that reduces packaging material. Ross, et al. proposes a solution to the problem of increased packing material by having the drape placed loosely within the kit

as opposed to being packaged within the kit. Therefore, modification of Ross, et al. so that the drape were instead placed into a container would increase the amount of packaging in Ross, et al. This modification would completely frustrate the intended purpose of Ross, et al. which is to do the exact opposite in reducing the amount of packaging material. Therefore, modification of the combination of Ross, et al., Rudnick, et al. and Harrison as set forth by the Examiner would render the references being modified unsatisfactory for their intended purpose and is not proper. As such, a case of prima facie obviousness has not been made.

# B2. THE CITED REFERENCES DO NOT TEACH OR SUGGEST ALL OF THE CLAIM LIMITATIONS.

To establish "prima facie" obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180, U.S.P.Q. 580 (CCPA 1974). In the present case, a container that includes a base member and a reclosable lid in which accessory items that include at least a drape are stored in the container is not taught or suggested by the prior art. In regards to motivation to modify the combination of <u>Rudnick</u>, et al., <u>Harrison</u> and <u>Ross</u>, et al. the Examiner sets forth in Paper No. 20040423 the following:

It would have been obvious to one having ordinary skill in the art in view of Ross, et al. '543 as modified to modify the container so the container is used to hold accessory articles such as the articles in col. 2, II. 40-43 of Ross, et al. '543 because the selection of the specific articles for the container would have been an obvious matter of design choice in as much as the resultant structures will work equally well.

The Examiner, however, has failed to present any evidence whatsoever for the assertion that it would have been obvious for one having ordinary skill in the art to

modify the resulting container obtained upon combining Ross, et al., Rudnick, et al., and Harrison in order to achieve some further modified container that holds a drape. The statement made by the Examiner in Paper No. 20040423 concerning motivation to modify the container obtained upon combination of Ross, et al., Harrison and Rudnick, et al. is no more than an unsupported conclusion and is not a reason upon which to base a § 103(a) rejection.

Nowhere in the Final Rejection (Paper No. 20040423) does the Examiner articulate the knowledge he states as being well known in the art to modify the container achieved upon combination of Ross, et al., Harrison and Rudnick, et al. in such a way so that the resulting container stores accessory items that include at least a drape. A prima facie case of obviousness cannot be maintained without such articulation. In re Sang Su Lee, 277 F.3d 1338, 1345, 61 U.S.P.Q.2d 1430, 17 (Fed. Cir. 2002) (stating that the determination of patentability on the ground of obviousness requires the Examiner to articulate and place on the record that which he relies on to assert to be general knowledge to negate patentability). See also in re Zurko, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001) (stating that in patentability determinations limitations of claimed inventions cannot be met with general conclusions about "basic knowledge" or "common sense" to one of ordinary skill in the art but must be found in concrete evidence of record).

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Absent Applicants' disclosure, there is simply no motivation for one skilled in the art to combine <u>Rudnick</u>, et

al., Harrison and Ross, et al. and then further modify this already combined device to obtain a container with a base member and a reclosable lid that stores an accessory item that includes at least a drape. The Examiner has failed to identify any prior art where such a combination and further modification is suggested. The only place that the Examiner could have obtained that motivation is through Applicants' own disclosure. However, in making an obviousness determination, to give one of ordinary skill in the art knowledge of the invention, where no prior art references convey or suggest that knowledge, "is to fall victim to the insidious effect of a hindsight syndrome where that which only the inventor taught is used against the teacher" W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1533, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983).

It is therefore the case that the Examiner has not found the recited claim elements in the prior art or found a proper suggestion or motivation to modify the prior art to achieve the invention as set forth in claims 15-23, 25 and 26. As such, a *prima facie* case of obviousness has not been made because all of the limitations have not been shown to be taught or suggested by the prior art. The Examiner is simply using Applicants' own disclosure against Applicants, and such hindsight reconstruction is not permitted.

Therefore, Applicants respectfully submit that independent claim 15 is patentable over the cited references. If an independent claim is non-obvious under 35 U.S.C. § 103(a), then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Claims 16-23, 25 and 26 are dependent claims that depend either directly or indirectly from independent claim 15 that is non-obvious under 35 U.S.C. § 103(a). Applicants therefore respectfully submit that claims 15-23,

25 and 26 are patentable under 35 U.S.C. § 103(a) in view of the prior art.

Applicants respectfully submit that the Final Rejection of claims 1-23, 25 and 26 should be reversed, and that these claims should be allowed to issue in a United States patent.

Respectfully submitted,

DORITY & MANNING, P.A.

Date: September 13, 2004

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#### <u>APPENDIX</u>

### **CLAIMS (AS AMENDED) INVOLVED IN APPEAL:**

1. A surgical kit, comprising:

a tray, said tray further comprising a plurality of recesses formed therein for receiving surgical articles useful in performing a particular surgical procedure;

a substantially rigid accessory item container received in a container recess defined in said tray said container configured for holding objects only inside of said container before being opened by a user;

said container recess defining a nesting location for said container;

said container comprising a base member and a lid configured with said base member, said container removable from said tray; and

a securing device configured between said base member and said lid.

- 2. The surgical kit as in claim 1, wherein said tray comprises side walls, said container recess defined by at least two of said tray side walls.
- 3. The surgical kit as in claim 2, wherein said tray comprises at least one bumper wall that extends generally transversely from one of said side walls defining said container recess, said bumper wall defining a side of said container recess.
- 4. The surgical kit as in claim 1, wherein said tray comprises a planar surface upon which said container rests.
- 5. The surgical kit as in claim 4, wherein at least one of said surgical article recesses is defined in said planar surface and covered by said container such that access to said respective article recess is provided only after removal of said container from said tray.

- 6. The surgical kit as in claim 1, wherein said container base member and lid are flexibly connected by a hinge member.
- 7. The surgical kit as in claim 6, wherein said base member and lid define a clam-shell configuration.
- 8. The surgical kit as in claim 1, wherein said lid is reclosable, said securing device comprising a mechanism that allows said lid to be repeatedly opened and closed relative to said base member.
- 9. The surgical kit as in claim 8, wherein said securing device comprises a male boss member defined on one of said lid and said base member, and a female recess into which said male boss member releasably engages defined on the other of said base member and said lid.
- 10. The surgical kit as in claim 1, wherein said container is formed of a substantially transparent material.
- 11. The surgical kit as in claim 1, wherein said container comprises any combination of prep swabsticks, lubricant package, ointment package, suture strands, surgical drape, and gauze pads.
- 12. The surgical kit as in claim 1, wherein said tray further comprises a removable cover.
- 13. The surgical kit as in claim 1, wherein said kit is a percutaneous endoscopic gastrostomy (PEG) kit.
- 14. The surgical kit as in claim 1, wherein said container base member and lid comprise peripheral edges that are kept spaced apart in a closed sate of said container by bosses disposed around at least one of said peripheral edges.

15. A percutaneous endoscopic gastrostomy (PEG) kit, comprising:

a tray comprising a plurality of recesses disposed therein, each said recess adapted to hold articles useful in performing a percutaneous endoscopic gastrostomy (PEG) procedure;

a container adapted to fit at least partially within the tray, the container adapted to rest upon a planar surface defined within said tray, said container comprising a base member and a reclosable lid; and

wherein said container stores accessory items useful in performing the PEG procedure, and wherein the accessory items include at least a drape.

- 16. The PEG kit as in claim 15, further comprising a cover adapted to be placed over the tray.
- 17. The PEG kit as in claim 15, wherein at least one of said article recesses is defined in a planar surface upon which said container sits such that access to said respective article recess is provided only after removal of said container from said tray.
- 18. The PEG kit as in claim 15, wherein said container base member and lid are flexibly connected by a hinge member.
- 19. The PEG kit as in claim 18, wherein said base member and lid define a clam-shell configuration.
- 20. The PEG kit as in claim 15, further comprising a securing device configured between said container base member and said lid.
- 21. The PEG kit as in claim 20, wherein said securing device comprises a male boss member defined on one of said lid and said base member, and a female recess into which said male boss member releasably engages defined on the other of

said base member and said lid.

- 22. The PEG kit as in claim 15, wherein said container is formed of a substantially transparent material.
- 23. The PEG kit as in claim 15, wherein said container comprises any combination of prep swabsticks, lubricant package, ointment package, suture strands, surgical drape, and gauze pads.
  - 24. (Allowed)
- 25. The PEG kit as in claim 15, wherein in a closed condition of said container, said base member and said lid are spaced apart along at least a portion of the periphery of said container to aid in sterilization of the articles within said container.
- 26. The PEG kit as in claim 25, further comprising at least one boss member disposed on at least one of said lid and said base member.